DEC - 1 2011

Attachment L - 510(k) Summary

Contact: Justin Eggleton
Musculoskeletal Clinical & Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
202.552.5800

Date Prepared: **October 13, 2011**

Device Trade Name: AccuLIF® TL-PEEK Cage

Manufacturer: CoAlign Innovation, Inc.
150 North Hill Drive, Suite 1
Brisbane, CA 94005

Common Name: Spinal intervertebral body fixation orthosis

Classification: 21 CFR §888.3080

Class: II

Product Code: MAX

Indications For Use:
Intervertebral Body Fusion Device: The CoAlign Innovations AccuLIF® TL-PEEK Cage is indicated for intervertebral body fusion with autogenous bone graft material in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have completed six months of non-operative treatment.

The CoAlign Innovations AccuLIF TL-PEEK Cage is always to be used with supplemental internal spinal fixation. Additionally, the CoAlign Innovations AccuLIF TL-PEEK Cage may be used with autogenous bone graft.

Device Description:
The CoAlign AccuLIF TL-PEEK Cage is expandable in-situ via a hydraulic system comprising two piston and cylinder arrangements. The device is expanded to the desired height by injecting saline into the cylinders. The device locks in 1mm increments as it expands. The device is provided non-sterile and must be sterilized prior to use.

The CoAlign AccuLIF TL-PEEK Cage device comes in two sizes, a 6mm height which expands up to 9mm and an 8mm height which expands up to 12 mm. Both sizes have a 12mm wide by 25mm long footprint. The device has fixation ridges on the top and bottom surface. It also has a graft opening window which extends from the bottom surface to the top surface. The device has

a proximal boss which has a threaded connection port for connecting to the inserter and a fluid port for transporting the expansion fluid. The device is expanded by using a disposable tubing set and pressure syringe. The device may be implanted through a standard anterior, posterior or transforaminal approach.

Identification of Predicates

- AccuLIF IBF Cage (K110270)
- Caliber IBF Cage (K102293)
- SEC IBF and VBR (K093669)

Summary of Technological Characteristics

AccuLIF TL-PEEK Cage is an expandable spacers made from Titanium-6AL-4V ELI alloy that conforms to ASTM F136, polyetheretherketone (PEEK Optima LT1) that conforms to ASTM F2016, 316LVM Stainless Steel that conforms to ASTM138-08, and Silicon Rubber (MED-4870). The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Expansion mechanism
- Structural support mechanism

Discussion of Testing:

The following non-clinical tests were conducted:

- Dynamic compression testing, conducted in accordance with ASTM F2077-03
- Dynamic shear testing, conducted in accordance with ASTM F2077-03
- Static compression testing, conducted in accordance with ASTM F2077-03
- Static shear testing, conducted in accordance with ASTM F2077-03
- Static Subsidence testing, conducted in accordance with ASTM F2267-04
- Static Expulsion testing, conducted in accordance with ASTM Draft Standard F-04.25.02.02
- Surgical technique validation, conducted in the same manner as the predicate surgical technique validation.

Conclusions:

The subject and predicate devices share the same indications for use, design, function, and materials of manufacture. The non-clinical test results demonstrate that any minor differences do not impact device performance as compared to the predicates. The AccuLIF TL-PEEK Cage was shown to be substantially equivalent to the AccuLIF IBF Cage (K110270), the Caliber IBF Cage (K102293), and the SEC IBF and VBR (K093669).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 1. 2011

CoAlign Innovation, Inc.
% Musculoskeletal Clinical &
Regulatory Advisers, LLC
Mr. Justin Eggleton
1331 H Street NW, 12th Floor
Washington, District of Columbia 20005

Re: K112095
Trade/Device Name: AccuLIF® TL-PEEK Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: November 23, 2011
Received: November 28, 2011

Dear Mr. Eggleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

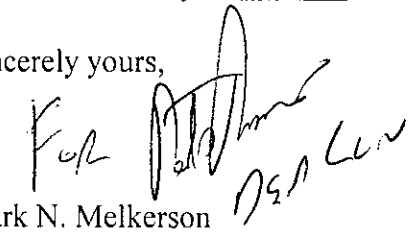
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112095

Device Name: AccuLIF TL-PEEK Cage

Intervertebral Body Fusion Device: The CoAlign Innovations AccuLIF® TL-PEEK Cage is indicated for intervertebral body fusion with autogenous bone graft material in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have completed six months of non-operative treatment.

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Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112095